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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,685	10/11/2005	Yukako Fukuhira	Q90825	3807

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EXAMINER	
HELM, CARALYNNE E	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
03/25/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/552,685	FUKUHIRA ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 13-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 11, 2011 has been entered.

Election/Restrictions

To summarize the current election, applicants elected group II without traverse.

Claim 1-3 and 13-18 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. John Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. (previously cited) in view of Maruyama et al. (previously cited), Zhao et al. (Journal of Applied Polymer Science 2003 90:1846-1850) and Berge et al. (Physical Review A 1990 41:6893-6902).

Shimomura et al. teach a honeycomb structured film comprised of biodegradable polymer and an amphiphilic polymer that acts as a surfactant (see paragraph 9; instant claim 4). Shimomura et al. go on to teach a set of biodegradable polymers that are suitable for use in the invention that include polycarbonates, polyethylene adipate, polyhydroxybutyric acid, polyethylene carbonate, and polybutylene carbonate (see paragraph 10; instant claims 5-7). Further the proportion of biodegradable polymer to amphiphilic polymer is taught to be between 1/1 and 50/1 (see paragraph 9; instant claim 12). Shimomura et al. do not explicitly teach a phospholipid as the amphiphilic compound or a lactic acid-glycolic acid copolymer as the biodegradable polymer.

Maruyama et al. also teach a honeycomb structured film comprised of polymer and an amphiphilic compound that acts as a surfactant (see page 855 column 1 paragraph 1). While Shimomura et al. teach amphiphilic copolymers for the preparation of these films, Maruyama et al. highlight that the amphiphilic compound can also be non-polymeric (see figure 1).

Zhao et al. also teach a honeycomb structured film composed of poly(lactic acid-co-glycolic acid) and an amphiphilic polymer (see figure 2 and page 1846 column 2 paragraph 1). They go on to teach the phenomenon responsible for the pattern formation is the same as that reported for gas bubbles in lipid monolayers as taught by Berge et al. In their teachings, Berge et al. use the phospholipid dipalmitoyl phosphorylcholine (DPPC) with a dye to construct the same sort of film pattern based upon the intersections of bubbles in a water based film (see figure 7 and page 6894 column 1 paragraph 3-column 2 line 3).

The phenomenon of film pattern formation in the system of Berge et al. as well as that of Shimomura et al., Maruyama et al. and Zhao et al. is parallel where droplets/bubbles of one phase form an array that is bordered by the components of a second phase creating a honeycomb patterned film. This process is dependant on the function of the amphiphilic compound and its dual hydrophilic and hydrophobic nature. Therefore it would have been obvious to one of ordinary skill in the art to exchange DPPC for the amphiphilic polymer in the invention of Shimomura et al. as the simple substitution of one known element for another to yield a predictable result. Additionally, the selection of poly(lactic acid-co-glycolic acid) as the biodegradable polymer would also have been obvious since it was known to be utilized in the same capacity for the preparation of such films. Therefore claims 4-8 and 12 are obvious over Shimomura et al. in view of Maruyama et al., Zhao et al., and Berge et al.

Claims 4-8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. in view of Maruyama et al., Nishikawa et al. (previously cited), and Berge et al.

Shimomura et al. teach a honeycomb structured film comprised of biodegradable polymer and an amphiphilic polymer that acts as a surfactant (see paragraph 9; instant claim 4). Shimomura et al. go on to teach a set of biodegradable polymers that are suitable for use in the invention that include polycarbonates, polyethylene adipate, polyhydroxybutyric acid, polyethylene carbonate, and polybutylene carbonate (see paragraph 10; instant claims 5-7). Further the proportion of biodegradable polymer to

amphiphilic polymer is taught to be between 1/1 and 50/1 (see paragraph 9; instant claim 12). Shimomura et al. do not explicitly teach a phospholipid as the amphiphilic compound or polylactic acid as the biodegradable polymer.

Nishikawa et al. teach a honeycomb structured film composed of a biodegradable polymer and amphiphilic polymer where polylactic acid and polycaprolactone are named as biodegradable polymers in the film (see page N11.7.3 paragraphs 1 and 2; instant claims 5-6 and 8).

Maruyama et al. also teach a honeycomb structured film comprised of biodegradable polymer and an amphiphilic compound that acts as a surfactant (see page 855 column 1 paragraph 1). While Shimomura et al. teach amphiphilic copolymers for the preparation of these films, Maruyama et al. highlight that the amphiphilic compound can also be non-polymeric (see figure 1).

Berge et al. use the phospholipid, DPPC, with a dye to construct the same sort of film pattern as that of Shimomura et al., Maruyama et al., and Nishikawa et al. based upon the intersections of bubbles in water based film (see figure 7 and page 6894 column 1 paragraph 3-column 2 line 3).

The phenomenon of film pattern formation in that of Berge et al. as well as that of Shimomura et al., Maruyama et al. and Nishikawa et al. is parallel where droplets/bubbles of one phase form an array that is bordered by the components of a second phase creating a honeycomb patterned film. This process is dependant on the function of the amphiphilic compound and its dual hydrophilic and hydrophobic nature. Therefore it would have been obvious to one of ordinary skill in the art to exchange

DPPC for the amphiphilic polymer in the invention of Shimomura et al. as the simple substitution of one known element for another to yield a predictable result. Additionally, the selection of polylactic acid as the biodegradable polymer would also have been obvious since it was known to be utilized in the same capacity for the preparation of such films. Therefore claims 4-8 and 12 are obvious over Shimomura et al. in view of Maruyama et al., Nishikawa et al., and Berge et al.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. in view of Maruyama et al., Nishikawa et al., and Berge et al. as applied to claims 4-8 and 12 above, and further in view of Kazakov et al. (US PGPub No. 2003/0044455).

Shimomura et al. in view of Maruyama et al., Nishikawa et al., and Berge et al. make obvious the film structure of instant claim 4 where DPPC is the amphiphilic compound. This modified reference does not explicitly teach phosphatidyl choline or L-α-phosphatidyl ethanolamine dioleoyl as the amphiphilic compound.

Kazakov et al. teach that DPPC, phosphatidyl choline, and dioleoylphosphatidylethanolamine (L-α-phosphatidyl ethanolamine dioleoyl) can be used for the same functionality as phospholipids (see paragraph 40; instant claims 9-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to select phosphatidyl choline or L-α-phosphatidyl ethanolamine dioleoyl instead of DPPC as an equivalent phospholipid for the amphiphilic compound in the

invention of Shimomura et al. in view of Maruyama et al., Nishikawa et al., and Berge et al. as the simple substitution of one known element for another to yield a predictable result. Therefore claims 9-11 are obvious over Shimomura et al. in view of Maruyama et al., Nishikawa et al., Berge et al., and Kazakov et al.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shimomura et al. in view of Maruyama et al., Zhao et al., and Berge et al. as applied to claims 4-8 and 12 above, and further in view of Kazakov et al.

Shimomura et al. in view of Maruyama et al., Zhao et al., and Berge et al. make obvious the film structure of instant claim 4 where DPPC is the amphiphilic compound. This modified reference does not explicitly teach phosphatidyl choline or L-α-phosphatidyl ethanolamine dioleoyl as the amphiphilic compound.

Kazakov et al. teach that DPPC, phosphatidyl choline, and dioleoylphosphatidylethanolamine (L-α-phosphatidyl ethanolamine dioleoyl) can be used for the same functionality as phospholipids (see paragraph 40; instant claims 9-11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to select phosphatidyl choline or L-α-phosphatidyl ethanolamine dioleoyl instead of DPPC as equivalent phospholipid for the amphiphilic compound in the invention of Shimomura et al. in view of Maruyama et al., Zhao et al., and Berge et al. as the simple substitution of one known element for another to yield a predictable result.

Therefore claims 9-11 are obvious over Shimomura et al. in view of Shimomura et al. in view of Maruyama et al., Zhao et al., Berge et al. and Kazakov et al.

Declaration

The declaration under 37 CFR 1.132 filed February 11, 2011 is insufficient to overcome the new grounds of rejection.

The prior art currently cited in the rejections motivates the selection of a phospholipid in general and phosphatidyl choline, L-α-phosphatidyl ethanolamine dioleoyl (DOPE), or DPPC in particular for the self-supported honeycomb film with biodegradable polymer of Shimomura et al. While the data in the declaration shows the inability of cholesterol at the tested concentration to yield a honeycomb structure when utilized as the amphiphilic compound in such an application, it is not sufficient to overcome the current rejection based upon the demonstrated functionality of a phospholipid to generate a honeycomb film because cholesterol is not a phospholipid. The inability of cholesterol to support the formation of the honeycomb structure does not represent the behavior of a phospholipid due to the difference in structure between a phospholipid and cholesterol. In addition, the experiment conducted was not commensurate in scope with the claims since a very large range of proportions of amphiphile to polymer are embraced for the films, but only a single value was tested. It is not clear that this one composition would be representative of the films produced with

a proportion of amphiphile to polymer of 1/1 to 1/1000 as is claimed. Therefore the declaration is unpersuasive.

Response to Arguments

Applicants' arguments, filed February 11, 2011, have been fully considered but they are moot in light of the new grounds of rejection. All previous grounds of rejection are hereby withdrawn in favor of the new grounds presented above based on the new references uncovered during a new search of the prior art.

Applicants recapitulate the discussion of the experimental data presented in the declaration that was addressed above. The formation of a honeycomb structure is not strictly unpredictable as applicants argue. Based upon the art currently of record, the artisan of ordinary skill in the art would have predicated that a phospholipid such as DPPC or DOPE would have been able to generate a honeycomb structure if employed in the invention of Shimomura et al. as the amphiphilic compound. The conditions concerning humidity, solvents, and film casting were established in the prior art for preparing the polymer films and these teachings would have been sufficient to enable the artisan of ordinary skill in the art to predictably make the claimed film with a phospholipid.

Applicants also argue that Maruyama et al. do not teach a honeycomb film composed of a polymer and amphiphile. Figure 2 shows such an organization where a polymer is combined with an amphiphile and utilized to prepare a honeycomb film. The

resulting complex is not covalently bound and is not itself a polymer, as applicants suggest, but two separate compounds that interact ionically with one another, where one is polymeric and the other is not.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Friday 9-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Juliet C Switzer/
Primary Examiner, Art Unit 1634